

REMARKS

Claims 1-11, 13-18 and 46-71 are currently pending in the application. Claims 1, 59, 60 and 62 have been amended and claims 11 and 66 have been cancelled herein. The Action rejected claims 1-9, 11 and 16 under 35 U.S.C. §102(b) as being anticipated by Green et al. (EP 0774237, hereinafter "Green"). The Action also rejected claims 10, 13-15, 17-18 and 46-66 under 35 U.S.C. §103(a) as being unpatentable over Green et al. (EP 0774237) in view of Hathaway et al. (USPN 5,304,184, hereinafter "Hathaway"). No acknowledgment of, nor reference to, pending claims 67-71 was made in the Action.

Objections to the Drawings

The drawings were objected to for failing to comply with 37 CFR 1.84(p)(5) because they do not include reference signs mentioned in the description. The description has been amended to eliminate reference to reference signs not mentioned in the specification. Specifically, 166 has been replaced with 166a and 166b and 264 has been replaced with 264a and 264b.

Objections to the Specification

The disclosure was objected to for failing to specify the co-pending application on page 12, and for improperly labeling the sheath on page 32. Accordingly, the co-pending application has been specified on page 12 and the proper sheath reference numeral is referred to on page 32.

In addition, the title was objected to for not being descriptive. Accordingly, the title has been replaced with Apparatus and Methods for Delivering a Vascular Closure Device to a Body Lumen.

Claim Objections

Claim 62 was objected to for a typographical error. The error has been corrected by a claim amendment to claim 62.

Rejections under 35 USC §112

Claim 59 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which Applicants regard as the invention. Claim 59 has been amended to correct a typographical error, specifically to replace "or the housing" with "from the housing."

Rejections under 35 USC §102

The Action rejected claims 1-9, 11 and 16 under 35 U.S.C. §102(b) as being anticipated by Green. Applicants respectfully request that this rejection be withdrawn, as Green fails to teach, suggest or disclose all of the elements of independent claim 1.

The present invention is directed towards medical apparatus and methods for delivering a vascular closure element, or annular clip, for closing a puncture in a blood vessel formed during a medical procedure. In a preferred embodiment of the present invention, a housing is provided for housing the clip and releasably holding the clip therein. In order to fasten the clip to the blood vessel and close the punctured region, the housing is slidably disposed over an exterior of an elongate member and actuable for advancing the clip distally towards the distal end of the elongate member.

Conversely, Green discloses a device having a clam shell style clip 22 slidable over a clip support fixture 34 by the axial translation of an elongate pusher tube 42 (Green, col. 7, paragraphs 19-20). The pusher tube 42 includes engagement fingers 44a and 44b which engage the rear of the clip 22 such that the clip 22 rests both on the support fixture and engagement fingers 44a and 44b. The pusher tube 42 pushes the clip 22 distally along the support fixture 34 and into contact with a blood vessel to be sealed. Neither the pusher tube 42 or the clip support fixture 34 house the clam shell clip 22, instead leaving the clip 22 entirely exposed to the interior of the body.

Each of the independent claims, either as previously presented or as currently amended, include a housing for housing the annular clip within. Claim 1, as amended, includes a housing slidably disposed on an exterior of the elongate member, the housing configured for housing the clip and releasably holding the clip, the housing being actuable for advancing the clip distally

towards the distal end of the elongate member. In addition, independent claim 46 refers to a housing configured for releasably holding a closure element therein, independent claim 55 refers to an annular clip releasably carried within the housing and claim 60, as amended, includes a housing releasably holding the clip therein.

Applicants respectfully assert that Green does not teach, suggest or disclose a slidable housing for housing the clip therein and for sliding distally along an elongate member. The Action compares the clip support fixture 34 to the housing of the present invention. The Action states that the support fixture 34 is "slidable with respect to the sliding of the assembly via [pusher tube] 42." Applicants respectfully disagree with this comparison, as the clip support fixture 34 clearly does not house the clip 22 therein, nor is the fixture 34 slidably disposed on an exterior of the elongate member for delivering the clip therefrom. Fixture 34 is not slidably disposed on an exterior of the tubular member 30. Instead, fixture 34 simply abuts the distal end of tubular member 30 and acts as an immovable extension of member 30 never moving in relation to the tubular member 30. Furthermore, the clip 22 rests over the fixture 34 and slides along the fixture 34, but the fixture 34 never houses or holds the clip 22. Any comparison of the claimed housing to the pusher tube 42 fails for similar reasons. Although the pusher tube 42 slides along the tubular member 30, the tube 42 does not house the clip 22, as is clearly shown in Figures 12 and 17 of Green. The clip 22 rests on top of the elongated fingers 44a and 44b, which form the pusher tube 42 (Green, Figures 12 and 17, paragraph 20), but the clip 22 is left entirely exposed while on the pusher tube 42.

Furthermore, claim 1 requires an annular clip. The clip 22 disclosed in Green is clearly a clam shell type configuration. Green acknowledges this by stating that the opposed clip legs 24a and 24b extend in a direction perpendicular to a blood vessel wall (Green, Col. 9, ll. 50-53). By extending only in one direction, that direction parallel to the vessel wall, the clip 22 in Green is not annular. Therefore, Applicants respectfully assert that Green fails to teach, suggest or disclose all of the elements of independent claim 1 and respectfully requests that this rejection be withdrawn.

Rejections under 35 USC §103

The Action rejected claims 10, 13-15, 17-18 and 46-66 under 35 U.S.C. §103(a) as being unpatentable over Green in view of Hathaway. Applicants respectfully request that this rejection be withdrawn, as both Green and Hathaway are not properly combinable, and Green and Hathaway, either alone or in combination, fail to teach, suggest or disclose all of the elements of independent claims 1, 46, 55 and 60.

Green and Hathaway are not properly combinable. First, each reference addresses different subject matter. Green is directed to an apparatus for applying a surgical clip to a blood vessel, while Hathaway is directed to a suturing device and method for suturing blood vessels. Green applies a clam shell type medical clip 22 to the exterior of a blood vessel to clamp an opening in that vessel (Green, Fig. 19). This clip 22 is provided by the apparatus internally within the body. Conversely, Hathaway advances needles 57 through the tissue membrane to suture the vessel opening, i.e., draw the opening closed with a threadlike suturing material 58 (Hathaway, Col. 5, ll. 59-64; Col. 7, ll. 9-55). The tying of the suture is performed by the doctor outside of the patients body (Hathaway, Figs. 14a-f). Furthermore, Hathaway is not directed towards surgical clips, and in fact never refers, explicitly or implicitly, to a surgical clip or the deployment of a surgical clip within a blood vessel.

Second, the distal end locator 53 in Hathaway would interfere with the proper operation of the device in Green. Specifically, when the locator 60 of Green is deployed within a vessel, the geometric plane defined by the locator 60 is oriented parallel to the elongation of the vessel (Green, Figure 15). The opposed clip legs 24a and 24b of clam shell type clip 22 extend in a direction perpendicular to the elongation of the blood vessel, such that the locator 60 pulls back a portion of the vessel wall extending parallel to the vessel. This allows the perpendicularly aligned clip legs 24a and 24b to adequately grab onto this pulled back tissue when the clip closes upon deployment (Green, Col. 9, ll. 48-53). Conversely, the distal end locator 53 of Hathaway deploys in an circular manner, such that when the distal end is pulled back, all of the tissue surrounding the distal end 53 is pulled back as well (Figs. 5 and 18-22). Therefore, this distal end 53 of Hathaway could not be used in the device of Green because the clam shell type clip 22 would have to deploy upon a circularly pulled back portion of the vessel wall, and not a portion

extending parallel to the vessel wall that is required to allow clip 22 to properly grab the vessel tissue upon closure. For these reasons, Hathaway is not properly combinable with Green.

Furthermore, Hathaway, either alone or in combination with Green, fails to disclose a housing for releasably holding a closure device therein. Hathaway discloses a device with an array of needles that carry a length of suture, the array being advanceable into the blood vessel to apply the sutures to the tissue surrounding the blood vessel opening (Hathaway, col. 2, lines 55-68). Hathaway is not directed towards vascular closure devices, and in fact never refers, explicitly or implicitly, to a vascular closure device or the deployment of a closure device within a blood vessel. It follows directly that, because Hathaway never discloses a closure device, Hathaway also fails to disclose a housing for releasably holding a closure device therein. As discussed with regard to the §102 rejection, Green also fails to teach, suggest or disclose a housing as recited in the claimed invention. Accordingly, because Hathaway and Green fail to teach, suggest or disclose a housing as recited in claims 1, 46, 55 and 60, and because Hathaway and Green are not properly combinable, Applicants respectfully request that the rejection to these claims be withdrawn.

Rejection to Claims Under the Doctrine of Obviousness-type Double Patenting

Applicants have filed a terminal disclaimer herewith to disclaim the portion of the patent term extending beyond that of U.S. Patent Nos. 6,623,510 and 6,277,140. Applicants therefore respectfully request that this rejection be withdrawn. Applicants note that in paragraph 15 of the action, Examiner issues a provisional obviousness-type double patenting rejection to application Serial No. 09/732,835. This is the serial number of the current application, therefore Applicants respectfully submit that this rejection is in error and request that the rejection be withdrawn. With respect to copending applications 10/081,725, 10/081,723 and 10/081,717, because Applicants submit that this application is now in allowable form, the provisional rejection with regard to these copending applications is the only remaining rejection. Therefore, Applicants respectfully request that the Examiner withdraw this provisional rejection for the present application in accordance with MPEP Section 804(I)(B).

Conclusion

Applicants respectfully assert that independent claims 1, 46, 55 and 60 are in allowable form. Furthermore, because claims 2-10, 13-18, 46-65 and 67-71 depend from the aforementioned independent claims, Applicants respectfully request that the rejections to those claims be withdrawn as well. Prompt and favorable action on the merits of the claims is earnestly solicited. Should the Examiner have any questions or comments, the undersigned can be reached at (949) 567-6700.

Respectfully submitted,

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